REMARKS

Claims 1-2, 4-7, 9-10, 12-16 and18 are pending, of which Claims 1-2, 4-7, 9-10 and 12-13 have been withdrawn from consideration. Claims 3, 8, 11 and 17 have been cancelled without prejudice or disclaimer. Claims 14-16 and 18 are presently under consideration,

1. The specification has been amended to overcome the noted informality regarding the use of the trademark TRIZMA on Pages 12, 17 and 18.

2. Claims 14-18 were rejected under 35 U.S.C. §112, first paragraph. In particular, it was noted that the claims are drawn to a vast genus of antibodies which can bind any lipoprotein of *Pseudomonas aeruginosa.*

The claims have now been amended to a specific lipoprotein and to a specific monoclonal antibody PS2. As noted below, the Applicant will make a deposit of such antibodies pending resolution of the remaining issues in this application. Therefore, it is respectfully submitted that Claims 14-16 and 18 are in full compliance with §112. Accordingly, it is respectfully requested that the rejection of Claims 14-18 under 35 U.S.C. §112, first paragraph, be withdrawn.

3. Claim 17 was rejected under 35 U.S.C. §112 first and second paragraphs. As noted in paragraph [0039] of the application, the monoclonal antibody PS2 was purchased commercially. Further, as noted in paragraph [0009] of the application, this monoclonal antibody was reported as one which recognized an outer membrane protein later identified as lipoprotein I of *Pseudomonas aeruginosa*. Finally, the

Applicant assures that a deposit of this monoclonal antibody will be made under the terms of the Budapest Treaty, upon allowance of the claims.

Therefore, it is respectfully submitted that the prior publications regarding PS2 monoclonal antibody and its deposit (to be made) are sufficient to render the subject matter of Claim 17 (now in Claim 1) in compliance with §112, first and second paragraphs. Accordingly, it is respectfully requested that the rejection of Claim 17 under 35 U.S.C. §112, first and second paragraphs, be withdrawn.

4. Claim 14 was rejected under 35 U.S.C. §103(a)* over Ansorg et al. (J. Clin. Microbiol., 20:84-88, 1984), and Claim 14-18 were rejected under 35 U.S.C. 103(a) over Ansorg et al. and Sciortino (Hybridoma, 12:327-332, 1993).

The present invention is directed to a kit for testing the presence of *Pseudomonas aeruginosa* in a sample. The kit includes an agglutination reagent and an antibody specific for lipoprotein I of *Pseudomonas aeruginosa*, wherein the antibody comprises monoclonal antibody PS2.

As noted in paragraph [0016] of the application, the present invention provides a rapid test for *Pseudomonas aeruginosa* that would allow its identification on the first day of culture. The test significantly reduces the turnaround time to about 18-20 hours, and is a single assay as opposed to a battery of tests required by the conventional methods. Further, it has a sensitivity of about 99.3% and specificity of about 95% (see paragraph [0020] of the application).

* The Office Action incorrectly states that the application names joint inventors. Correction of same is respectfully requested.

It is respectfully submitted that Ansorg et al. do not disclose or suggest the claimed kit for testing the presence of *Pseudomonas aeruginosa*.

As noted by the Examiner, Ansorg et al. disclose a coagglutination test for P. *aeruginosa* flagellar H antigens. And, while flagellar H antigens may be lipoproteins (as pointed out by the Examiner), they are not synonymous with lipoprotein I (LPI). LPI is distinctly different from flagellar proteins described by Stanislavsky et al. (referenced by the Examiner on Page 8 of the Office Action). It is a completely different lipoprotein and has no functional or biological homology with flagellar H antigens.

Moreover, it is respectfully submitted that Ansorg et al. do not teach or suggest an agglutination test for LPI. In this regard, it is respectfully submitted that extraction of LPI is a difficult task, as pointed out by Hancock et al. (referenced by the Examiner on Page 8 of the Office Action). In view of this difficulty, the artisans in the art have not yet been successful at both extraction of the antigen and creating an amino assay for it. Extraction of LPI renders it is immunologically non-reactive without the ability to retain its immuno-reactive properties. The extraction and reaction buffers (reagents), as in the present invention, have a unique formulation that provides for extraction and further immuno-reaction with the PS2 monoclonal antibody. The prior art completely fails to teach or suggest a successful extraction and immunoassay for LPI, prior to the work done by present inventor.

In this regard, the Examiner noted the present invention to be in an unpredictable art. Therefore, how and why the test for P. *aeruginosa* disclosed in Ansorg et al. for H antigens, would work for a completely different lipoprotein, LPI, as in the present invention, has not been demonstrated. The Examiner's statement that "...it is standard to put necessary reagents together in a useful form for ease of use." amounts to hindsight reconstruction prohibited by law. In other words, the Examiner has used the Applicant's own invention to make a rejection under 35 USC §103, which is improper.

In summary, the Examiner has failed to make a *prima facie* case of obviousness by not showing a teaching or suggestion in the prior art of the claimed invention. As the Federal circuit has ruled that the Examiner may not use the patent application as a basis for the motivation to modify the prior art to reconstruct the claimed invention (ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984) and that both the suggestion and reasonable expectation of success must be found in the prior art, and not in the applicant's disclosure (In re Dow Chem. Co., 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988).

Further, with respect to Ansorg et al., the Examiner admitted that they do not disclose a reagent for extracting the lipoprotein from *Pseudomonas aeruginosa*, that the monoclonal antibody is not PS2, and that the reagents required for the agglutination test are not disclosed as a kit. Further, as pointed out above, Ansorg et al. do not relate to LPI lipoprotein. Therefore, why one of ordinary skill in the art would choose to

use the teachings of Ansorg et al., absent the Applicant's invention, is not shown or explained.

In view of the above, it is respectfully submitted that Claims 14-16 and 18 are not obvious over Ansorg et al. and Sciortino, alone or in any combination thereof.

Withdrawn method Claims 1-2, 4-7, 9-10 ad 12-13, have been amended to include the allowable subject matter of product claims. Therefore, it is respectfully requested that these claims be rejoined in accordance with the provisions of MPEP §821.04.

PROPRIETARY INFORMATION DISCLOSURE STATEMENT

The Examiner is respectfully requested to return an initialed copy of Page 2 of Form PTO-1449 filed with the IDS on April 28, 2006, further indicating review and consideration of WO 00/52203/A2/A3 and WO 01/02577 A1 references. In addition, attached hereto is another copy of the Commonwealth Biotechnologies publication, which was filed with the IDS on April 28, 2006. An initialed copy of Page 5 of the same 1449 form is also respectfully requested.

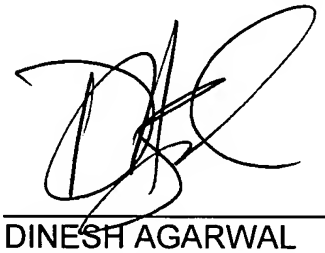
CONCLUSION

For the foregoing reasons, it is respectfully submitted that Claims 1-2, 4-7, 9-10, 12-13, 14-16 and 18 are in condition for allowance. Withdrawal of all the rejections and allowance of these claims are earnestly solicited.

It is believed that no additional fee is due for this submission. Should that determination be incorrect, however, the Commissioner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully submitted,



DINESH AGARWAL
Attorney for Applicant(s)
Reg. No. 31,809

Law Office - Dinesh Agarwal, P.C.
5350 Shawnee Road, Suite 330
Alexandria, Virginia 22312
Telephone: (703) 642-9400
Fax: (703) 642-9402

DA/va

Commonwealth Biotechnologies, Inc.

Commonwealth Biotechnologies, Inc. (CBI) is the most comprehensive Contract Research Organization in the market today, offering cutting- edge expertise and a complete array of the most current analytical and synthetic chemistries and biophysical technologies, many of which are not available from any other source. Our broad technology base coupled with the assignment of an experienced senior scientist to oversee every project allows CBI to offer **true customized project design and management** to support your specific needs.

CBI's fully automated instrumentation offers rapid turnaround time and accurate results. You have complete access to an experienced staff of highly skilled molecular biologists, geneticists, biochemists, and chemists to respond to your questions about protocols, results, or pricing.

PCR Based Human Herpes Virus Analysis Now Available!

Microbiology and Food Safety Services Now Available!

Anthrax Testing Service	Genome Services	AccuTrac	Paternity Testing
	Order	Quotation	Employment

Commonwealth Biotechnologies, Inc.
601 Biotech Drive, Richmond, VA 23235
800-735-9224 (800-RELY-CBI) FAX: 804-648-2641
Toll-free Fax on Demand: 877-329-4224 (877-FAX- 4CBI)
email: info@cbi-biotech.com

http://www.biotechcanada.cbi-biotech.com/